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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,557

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EXAMINER

HINES, JANA A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,557	Applicant(s) NASH ET AL.	
	Examiner JaNa Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-10,42 and 45-60 is/are pending in the application.
- 4a) Of the above claim(s) 54-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-10,42 and 45-53 is/are rejected.
- 7) ☒ Claim(s) 49 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 30, 2008 has been entered.

Amendment Entry

2. The amendment filed August 11, 2008 has been entered. Claims 1 and 42 have been amended. Claims 2-4, 6, 11-41, and 43-44 are canceled. Claims 49-60 have been newly added.

Election/Restrictions

3. Newly submitted claims 54-60 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the Inventions are related as distinct methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes and this same method was previously restricted. Therefore, the inventions are unrelated. Additionally, searching the inventions together would impose a serious search burden. In the instant case, the search of the inhibitors, methods of

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production, and methods for decreasing animal respiratory illness are not coextensive. Thus the product and method of production of Group I requires a different search than the method for decreasing animal respiratory illness. Searching for a method for decreasing an animal's respiratory illness by mixing the separated contents of the harvested egg and administering the mixed contents to an animal whereby the antibody to the immunogen inhibits adherence of the immunogen is not necessary for a determination of novelty and unobviousness of the product of Group I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 54-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 1, 5, 7-10, 42 and 45-53 are under consideration in this office action.

Request for Information

5. Applicant refers to the results of the invention being predicated on the inhibitors' binding characteristics as described in the paper entitled "Natural Solutions for Animal Agriculture". The paper filed August 11, 2008 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office. There is no citation information associated with this paper and the paper is not listed on the IDS submitted May 30, 2008. Therefore the paper has been placed in the application file, but the information

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referred to therein has not been considered. Thus it is requested that Applicant provide the appropriate citation data, including the date.

Response to Arguments

6. Applicant's arguments filed October 3, 2007 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 5, 7-10, 42, 45-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a microbial adherence inhibitor or method of producing the inhibitor for administration to swine to inhibit the adherence of colony-forming organisms with respiratory organisms comprising swine influenzae (H1N1, H3N2), *P. multocida*, *P. haemolytica*, *M. haemolytica*, *M. hypopneumoniae*, *H. suis*, *H. somnus*, *H. parasuis* and *H. planopneumonia* in the respiratory tracts of said animals produced by the method of: A) Inoculating female birds, in or about to reach their egg laying age, with a targeted

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colony-forming organisms from said class of respiratory viruses comprising swine influenzae (H1N1, H3N2); B) Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming organisms from the class of respiratory viruses comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C) Harvesting the eggs laid by the birds; D) Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness-causing organisms in the respiratory tracts of swine.

Applicant did not point to support in the specification for a microbial adherence inhibitor or method of producing the inhibitor for administration to swine to inhibit the adherence of colony-forming organisms with respiratory viruses comprising swine influenzae (H1N1, H3N2), *P. multocida*, *P. haemolytica*, *M. haemolytica*, *M. hypopneumoniae*, *H. suis*, *H. somnus*, *H. parasuis* and *H. planopneumonia* in the respiratory tracts of said swine produced by the method. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of a microbial adherence inhibitor that inhibits the adherence of the organisms. Thus, there appears to be no teaching of a microbial adherence inhibitor that inhibits the adherence of the organisms. Applicant has not pointed to any pages of the instant specification and claims for support of the amendment drawn to the microbial adherence inhibitor that inhibits the adherence of the organisms. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line

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number support for the identity of a microbial adherence inhibitor that inhibits the adherence of the organisms as recited by the amendments. Therefore, the claims incorporate new matter and are accordingly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 5, 7-9, 42, 45-47 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054) in view of Okuno et al., (US Patent 6,337,070).

The claims are drawn to a microbial adherence inhibitor for administration to swine to inhibit the adherence of colony-forming organisms with a class of respiratory organisms comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of said swine produced by the method of: A) Inoculating female birds, in or about to reach their egg laying age, with a targeted colony-forming organisms from said class of respiratory viruses comprising swine influenzae (H1N1, H3N2); B) Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming organisms from the class of respiratory organisms

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comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C) Harvesting the eggs laid by the birds; D) Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness-causing organisms in the respiratory tracts of swine.

The rejection is on the grounds that it would have been *prima facie* obvious to one ordinary skill in the art at the time the invention to modify the microbial adherence inhibitor for administration to animals to inhibit the adherence of colony-forming organisms with a class of respiratory organisms comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of swine as taught by Lee and incorporate inoculation with respiratory viruses comprising swine influenzae (H1N1, H3N2) as taught by Okuno et al., in order to have antibody containing contents that have cross-recognizing ability for influenzae virus A virus subparticles.

The recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

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Furthermore, product by process claims are not limited to the manipulations of the recited steps, rather it is the structure that is implied by those steps. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

In this case, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Lee teach the desire to

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produce IgY, IgA and IgM antibody containing products using for pharmaceutical applications for the treatment of other animals. Moreover, it would have been prima facie obvious to combine the invention of Lee and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious viral illness in animals because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art the time of the invention.

9. Claims 1, 5, 7-9, 42, 45-47 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Okuno et al., (US Patent 6,337,070).

The claims are drawn to a microbial adherence inhibitor for administration to swine to inhibit the adherence of colony-forming organisms with a class of respiratory organisms comprising swine influenzae (H1N1, H3N2) in the respiratory tracts of said swine produced by the method of: A) Inoculating female birds, in or about to reach their egg laying age, with a targeted colony-forming organisms from said class of respiratory viruses comprising swine influenzae (H1N1, H3N2); B) Allowing a period of time sufficient to permit the production in the bird of antibody-containing contents in the bird's eggs to the targeted colony-forming organisms from the class of respiratory organisms comprising swine influenzae (H1N1, H3N2), said antibody in the eggs including IgY

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immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs; C) Harvesting the eggs laid by the birds; D) Separating the antibody-containing contents of said eggs from the shells thereby creating the microbial adherence inhibitor that binds to colony-forming illness-causing organisms in the respiratory tracts of swine.

The rejection is on the grounds that it would have been *prima facie* obvious to one ordinary skill in the art at the time the invention incorporate inoculation with respiratory viruses comprising swine influenzae (H1N1, H3N2) as taught by Okuno et al., to the microbial adherence inhibitor and method of Tokoro in order to have antibody containing contents that have cross-recognizing ability for influenzae virus A virus subparticles.

In response to an argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Thus it is the position of the Office that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Tokoro teach using viruses, as the targeted colony forming organisms, along with the desire to produce antibody containing products useful for the treatment of swine.

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Furthermore, it would have been prima facie obvious to combine the invention of Tokoro and Okuno et al., to advantageously achieve virus neutralization activity and protection against infectious viral illness in swine because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art the time of the invention.

10. Claims 8-10, 46-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US Patent 5,367,054), Okuno et al., (6,332,070) and Coleman (US Patent 5,585,098) further in view of Ishihara et al., (US Patent 6,068,862).

The rejection is on the grounds that Lee, Okuno et al., Coleman and Ishihara et al., teach methods drawn to a mixing and pasteurization step; a storage step; and carrier material being distilled dried grains or dried beet pulp.

In this case, it would have been obvious to one ordinary skill in the art at the time the invention was made to mix animal feed such as grains as taught by Ishihara et al., with Lee, Okuno et al., and Coleman in order to prevent and treat illness in swine as taught by Lee, Okuno and Coleman. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Lee, Coleman and Ishihara et al., teach treating swine with microbial adherence inhibitors as a means of immunizing animals against organisms. One having ordinary skill in the art would have been motivated to do this because the Ishihara et al., teach the animal feed

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additives being mixed with carrier the materials of animal feed improves intestinal functions, feed efficiency and eliminates malodor. Finally it would have been prima facie obvious to combine the invention of Lee, Okuno, Coleman and Ishihara et al., to advantageously achieve protection against infectious viral illness in swine.

New Grounds of Objection

Claim Objections

11. Claims 49 and 53 is objected to because of the following informalities:

a) Claim 49 recites abbreviations like *P. multocida*, *P. haemolytica*, *M. haemolytica*, *M. hypopneumoniae*, *H. suis*, *H. somnus*, *H. parasuis* and *H. planopneumonia* which must be spelled out when used for the first time in a chain of claims.

b) Claim 53 is dependant upon claim 53. Appropriate correction is required.

New Ground of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 10, 48 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a) Claims 10, 48 and 53 recite alternative limitations which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

Conclusion

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645